



Election/ # 7
11-502

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of) Examiner: Misook Yu
Donald L. Durden) Art Unit: 1642
Serial No. 09/870,379) Response to Paper No: 6
Filed: May 30, 2001)
For: "Compositions And Methods)
For Identifying Agents)
Which Modulate PTEN)
Function and PI-3 Kinase)
Pathways")

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TRAVERSAL OF RESTRICTION REQUIREMENT

A restriction requirement under 35 U.S.C. §121 was set forth in the Official Action dated August 13, 2002 in the above-identified patent application. It is the Examiner's position that claims 1-88 in the present application are drawn to twenty-seven (27) patentably distinct inventions which are as follows:

Group I: Claims 1-4, drawn to method to identify agents that modulate PTEN activity by assaying AKT, classified in 435, subclass 6.

Group II: Claim 5, drawn to agent(s) identified by group I invention, unclassifiable because of unknown nature of the agent(s).

Group III: Claims 6-12, drawn to method of gene therapy for treatment of cancer using PTEN gene, classified in class 514, subclass 44.

Group IV: Claims 13-17, drawn to method to identify agents that modulate PTEN activity by assaying microvessel density formation, classified in class 435, subclass 4.

- Group V: Claim 18, drawn to agent(s) identified by group IV invention, unclassifiable because of unknown nature of the agent(s).
- Group VI: Claims 19-22, drawn to method to identify agents that modulate PTEN activity by assaying TSP-1, classified in 435, subclass 6.
- Group VII: Claim 23, drawn to agent(s) identified by group VI invention, unclassifiable because of unknown nature of the agent(s).
- Group VIII: Claims 24-27, drawn to method to identify agents that modulate PTEN activity by assaying VEGF-1, classified in 435, subclass 6.
- Group IX: Claim 28, drawn to agent(s) identified by group VIII invention, unclassifiable because of unknown nature of the agent(s).
- Group X: Claims 29-32, drawn to method to identify agents that modulate PTEN activity by assaying TIMP3, classified in 435, subclass 6.
- Group XI: Claim 33, drawn to agent(s) identified by group X invention, unclassifiable because of unknown nature of the agent(s).
- Group XII: Claims 34-37, drawn to method to identify agents that modulate PTEN activity by assaying MMP-9, classified in 435, subclass 6.
- Group XIII: Claim 38, drawn to agent(s) identified by group X invention, unclassifiable because of unknown nature of the agent(s).

Group XIV: Claims 39-42, drawn to method to identify agents that modulate PTEN activity by assaying invasiveness of cells, classified in 436, subclass 62.

Group XV: Claim 43, drawn to agent(s) identified by group X invention, unclassifiable because of unknown nature of the agent(s).

Group XVI: Claims 44-48, drawn to method to identify agents that modulate PTEN activity by assaying PTEN phosphatase activity, classified in 435, subclass 21.

Group XVII: Claims 49-55, drawn to method to identify agents that modulate PTEN activity by chemical combinatorial library, classified in 435, subclass 4.

Group XVIII: Claims 56-60, drawn to method of preventing or inhibiting inflammatory disease using PTEN agonist, unclassifiable due to unknown nature of the agonist.

Group XIX: Claims 61-68, drawn to method of cancer treatment using unidentified PTEN agonist or using the agonist in combination with a chemotherapeutic agent, unclassifiable due to unknown nature of the agonist.

Group XX: Claims 69, and 86-88, drawn to in vivo method of inhibiting p53-mediated apoptosis using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

Group XXI: Claim 70, drawn to in vivo method of enhancing chemosensitivity of tumor cells to a patient having chemo-resistant tumor using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

Group XXII: Claim 71, drawn to in vivo method of enhancing radiosensitivity of tumor cells to a patient having radio-resistant tumor using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

Group XXIII: Claims 72-74, drawn to method of gene therapy using native PTEN for the treatment of inflammatory condition in a patient having a mutation in PTEN, classified in class 514, subclass 44.

Group XXIV: Claims 75-77, drawn to in vivo method of inhibiting immunoreceptor signaling using PTEN agonist, unclassifiable due to unknown nature of the small molecule.

Group XXV: Claims 78 and 79, drawn to in vivo method of augmenting an immune reaction using PTEN inhibitor, unclassifiable due to unknown nature of PTEN inhibitor.

Group XXVI: Claims 80-83, drawn to in vivo method of inhibiting aberrant angiogenesis using PI3 inhibitor, unclassifiable due to unknown nature of the inhibitor.

Group XXVII: Claims 83-85, drawn to in vivo method of inhibiting aberrant angiogenesis using either AKT

inhibitor or AKT inhibitor in combination with PI3 inhibitor, unclassifiable due to unknown nature of the inhibitors.

Applicant respectfully traverses the restriction between the group I, IV, VI, VIII, X, XII, XIV, XVI and XVII inventions. A withdrawal or modification of the restriction requirement is clearly in order for the reasons set forth below.

According to the MPEP §803.01, there are two criteria for restriction between inventions which are alleged to be patentably distinct: 1) the inventions must be independent and distinct as claimed and 2) there must be a serious burden on the Examiner if the restriction is not required. The Examiner contends the group I, IV, VI, VIII, X, XII, XIV, XVI and XVII inventions are allegedly unrelated. According to M.P.E.P. §802.01:

The term "independent" (i.e. not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect...

Applicant respectfully submits that the assay methods claimed in groups I, IV, VI, VIII, X, XII, XIV, XVI and XVII are all related in that the methods will result in a similar effect, i.e. in the identification of modulators of PTEN activity. Significantly, the Examiner has placed the groups in similar subject matter classifications. Indeed, groups I, VI, VIII, X, and XII are in the exact same subject matter classification and, thus, the Examiner's workload would not be unduly increased by searching the invention as presently claimed. Accordingly, Applicant requests that the restriction between group I, IV, VI, VIII, X, XII, XIV, XVI and XVII inventions be withdrawn.

Similarly, Applicant respectfully traverses the restriction between the groups I and II, IV and V, VI and VII, VIII and IX, X and XI, XII and XIII, and XIV and XV

inventions. Applicant respectfully submits that each of the paired groups set forth above are related in that they comprise product by process claims. Accordingly restriction between these groups of claims is clearly improper.

Applicant also respectfully asserts that as a non-profit university, it is unduly burdensome, costly, and unreasonable to expect applicant to file 27 separate patent applications to protect the subject matter claimed in the present application.

In order to be fully responsive to the Official Action, however, Applicant hereby elects the Group XXVI invention, namely claims 80-83. Applicant elects the species of cancer.

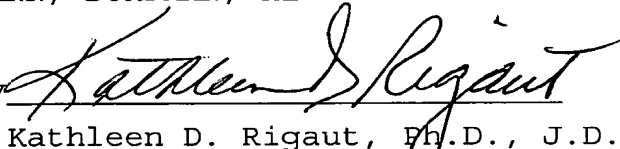
Applicant hereby reserves the right to file one or more continuation applications under 35 U.S.C. §120 on the subject matter of all claims ultimately withheld from consideration in the present application.

Early and favorable action on this application is earnestly solicited.

Respectfully submitted,

DANN, DORFMAN, HERRELL AND SKILLMAN

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